

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC.,

Plaintiff,

v.

WATSON PHARMACEUTICALS, INC.,
WATSON LABORATORIES, INC., and
WATSON PHARMA, INC.,

Defendants.

Civil Action No. 09-724-SLR

REDACTED

**PLAINTIFF CEPHALON, INC.'S BRIEF IN OPPOSITION TO DEFENDANTS'
MOTION FOR LEAVE TO FILE AN AMENDED ANSWER AND
COUNTERCLAIMS**

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I. INTRODUCTION

When the Federal Circuit observed over 20 years ago that inequitable conduct had become an “absolute plague”¹ in patent litigation, it was cases like this the Court must have had in mind. In their proposed amended answer and counterclaim, Defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. and Watson Pharma, Inc. (collectively, “Watson”) accuse ’981 patent inventor Dr. Hao Zhang and his supervisor, Mr. Lynn Maland (who is not an inventor), of perpetrating a fraud on the Patent Office by intentionally withholding the Stanley ’497 patent from the examiner. Discovery is closed, and Watson brings this pleading with the benefit of a record of over 150,000 pages of documents, almost three days of testimony from Dr. Zhang, a day of testimony from Mr. Maland, and testimony from eight other witnesses. What evidence has Watson adduced to support their attack on the integrity of these two scientists? What evidence has Watson uncovered that they knew of the information disclosed by this reference, and of its supposed materiality? Watson alleges nothing—nothing beyond “*information and belief*” that the accused even knew of the Stanley ’497 patent, let alone read and understood its supposed importance to patentability.

Watson alleges no facts from this extensive record to support its bare allegations of knowledge and intent to deceive—but that is not to say there are no facts. Indeed, when Watson’s counsel pressed Dr. Zhang at his deposition, Dr. Zhang told him [REDACTED.] After receiving this answer, Watson’s counsel did not even bother to show Dr. Zhang the ’497 patent or ask him a single specific question about it, yet Watson accuses Dr. Zhang of deliberately withholding the ’497 patent from the patent examiner with intent to deceive. As Plaintiff Cephalon, Inc. (“Cephalon”) shows below, the same is true for Mr. Maland. Indeed,

the only apparent reason for charging Mr. Maland with hiding the Stanley '497 patent—a reference that Watson cannot even allege he knew existed—is that Mr. Maland had the misfortune of being the last person deposed in fact discovery. His late deposition apparently made him the necessary vehicle to justify seeking the instant amendment now, over a month after the close of fact discovery and long after the date for amendment of pleadings.

Given the lack of any evidentiary support for its allegation of inequitable conduct, it is not surprising that Watson's proposed pleading fails to allege fraud with particularity as required by Fed. R. Civ. P. 9(b). Watson also does not demonstrate the good cause required by Fed. R. Civ. P. 16(b) to justify this late pleading. Finally, Watson fails to state a claim upon which relief could be granted, and the amendment is therefore futile under Fed. R. Civ. P. 15(a). Accordingly, Cephalon respectfully requests that the Court deny Watson's motion for leave to amend for at least these reasons, and for the reasons set forth below.

II. NATURE AND STATE OF THE PROCEEDINGS

This is an action for a declaratory judgment of infringement of U.S. Patent No. 6,264,981 (the "'981 patent") arising out of Watson's submission of an Abbreviated New Drug Application ("ANDA") for a fentanyl buccal tablet that is a generic of Cephalon's FENTORA[®] breakthrough cancer pain medication. Cephalon filed its complaint on September 25, 2009. (D.I. 1.) Watson answered Cephalon's complaint on October 19, 2009. (D.I. 10.) The deadline to join other parties and amend the pleadings was December 4, 2009. (D.I. 23.) Fact discovery in this action closed on January 19, 2010. (D.I. 41.)

On February 26, 2010, Watson moved for leave to amend its answer to add a counterclaim and affirmative defense for unenforceability of the '981 patent based on Dr. Zhang and Mr. Maland's alleged inequitable conduct before the Patent Office during the

¹ *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

prosecution of the '981 patent. (D.I. 53.) This brief is Cephalon's opposition to Watson's motion.

A *Markman* claim construction hearing in this action is scheduled for April 26, 2010. (D.I. 182.) Trial is scheduled to begin on May 10, 2010. (D.I. 23.)

III. STATEMENT OF FACTS

A. Background on the '981 Patent, Hao Zhang and Lynn Maland

Patent Application No. 09/428,071 (the "'071 application") was filed on October 27, 1999, and issued as the '981 patent on July 24, 2001. (D.I. 53, Exh. A at ¶ 15.) Dr. Zhang and Mr. Jed Croft are the named inventors on the '981 patent, and were employees of Anesta Corp. ("Anesta") at the time the '071 application was filed. (*Id.* at ¶ 75.) Mr. Maland was also an Anesta employee, and was Dr. Zhang's supervisor at the time the '071 application was filed. (*Id.* at ¶¶ 53, 57.)

B. Facts Related to the Alleged Inequitable Conduct

1. Watson was afforded a complete opportunity to take discovery

During the fact discovery period Watson took the depositions of ten witnesses. Cephalon agreed to extend fact discovery to allow Watson to depose all the witnesses it had noticed. Watson deposed Dr. Zhang for almost three days, on December 10 and 11, 2009, and January 14, 2010. Watson deposed Mr. Maland on January 19, 2010. During the fact discovery period Cephalon produced over 150,000 pages of documents in response to Watson's discovery requests.

2. Watson developed no evidence that Dr. Zhang or Mr. Maland had knowledge of the information disclosed in the Stanley '497 patent

Dr. Theodore Stanley and Mr. Brian Hague are listed as the inventors of the supposedly material reference—U.S. Patent No. 5,288,497 (the "'497 patent")—and a number of other

patents. Dr. Stanley was a founder of Anesta and a named inventor on several patents (collectively, the “Stanley patents”). (D.I. 53, Exh. A at ¶¶ 75, 83; [REDACTED].) Mr. Hague is also listed as a named inventor on the Stanley patents, and was an employee at Anesta at the time the inventions claimed in the Stanley patents were developed. (D.I. 53, Exh. A at ¶¶ 75, 83; [REDACTED].) During prosecution of the ’981 patent, the applicants filed an Information Disclosure Statement disclosing one of the Stanley patents, U.S. Patent No. 5,132,114 (the “’114 patent”). The ’497 patent, which Watson alleges is material, is in the same patent family as the ’114 patent.²

In deposition Watson asked Dr. Zhang [REDACTED.] In the three days Watson deposed Dr. Zhang, it did not ask him any specific questions about the ’497 patent, nor even mark the ’497 patent as an exhibit. Watson also did not put the ’114 patent in front of Dr. Zhang during his deposition, or ask Dr. Zhang any questions about this patent.

Watson also asked Mr. Maland in deposition whether [REDACTED.] U.S. Patent No. 4,671,953 (the “’953 patent”) to Stanley and Hague was issued on June 9, 1987, and discloses a lollipop-type formulation made with a cooked solution process. (Exh. E at 9:23-64.) Thus, [REDACTED.] As with Dr. Zhang, Watson did not ask Mr. Maland any specific questions about the ’497 patent, nor even mark the ’497 patent as an exhibit. Watson also did not put the ’114 patent in front of Mr. Maland during his deposition, or ask Mr. Maland any questions about this patent.

² Watson’s theory is that because the applicants cited the Stanley ’114 patent in an Information Disclosure Statement filed during prosecution of the ’981 patent, it must follow that Dr. Zhang and Mr. Maland knew of (and hid) the Stanley ’497 patent from the Patent Office. (D.I. 53, Exh. A at ¶¶ 76, 82-84.) As Cephalon discusses below, there is no evidentiary foundation for this inference.

3. Watson's pleading alleges knowledge and intent on information and belief after the close of fact discovery

On February 26, 2010, over one month after the close of fact discovery, and almost three months after the date set in the Scheduling Order to amend pleadings, Watson moved for leave to amend its answer to add a counterclaim and affirmative defense for unenforceability of the '981 patent based on Cephalon's purported inequitable conduct before the Patent Office. (D.I. 53.) Watson's proposed amended pleading alleges that the '981 patent is unenforceable because Dr. Zhang and Mr. Maland owed a duty of candor to the Patent Office, and breached this duty by failing to disclose the '497 patent to the Patent Office during prosecution of the '071 application with the intent to deceive. (D.I. 53, Exh. A at ¶¶ 51, 53, 67.)

Watson's proposed amended pleading alleges that the '497 patent was material to the patentability of the '981 patent. (*Id.* at ¶¶ 68-73.) The proposed pleading also alleges, ***upon information and belief***³, that Dr. Zhang and Mr. Maland had actual knowledge of the '497 patent. (*Id.* at ¶¶ 74, 78.) The proposed pleading also alleges, ***again upon information and belief***, that Dr. Zhang and Mr. Maland withheld the '497 patent from the Patent Office with the intent to deceive. (*Id.* at ¶ 82.) As explained below, the facts alleged in Watson's proposed inequitable conduct counterclaim do not reasonably support these allegations made on information and belief.

IV. SUMMARY OF THE ARGUMENT

1. Watson's motion for leave to amend should be denied because its proposed amendment fails to meet the pleading requirements for inequitable conduct. Inequitable

³ Pleading upon "information and belief" is grounded in Fed. R. Civ. P. 11(b), which requires attorneys making representations to the Court to certify, to the best of their knowledge, information, and belief, that any factual contentions have evidentiary support, or "will likely have evidentiary support after a reasonable opportunity for further investigation or discovery."

conduct must be pled with particularity under Fed. R. Civ. P. 9(b). Watson's proposed pleading alleges no facts that either Dr. Zhang or Mr. Maland (1) had actual knowledge of the allegedly material information, or (2) withheld this information with the intent to deceive the Patent Office. Watson instead alleges these required elements of an inequitable conduct claim only "upon information and belief" and further fails to specify any facts upon which this alleged belief could be reasonably based. Furthermore, Watson's belief is contradicted by the only relevant information in the record, [REDACTED.] Watson's motion should be denied because its proposed inequitable conduct claim fails to meet the pleading standards of Rule 9(b).

2. Watson has also failed to show the good cause required to modify the Court's Scheduling Order under Fed. R. Civ. P. 16(b), because Watson has not diligently pursued its proposed inequitable conduct claim. Instead, although Watson had a full opportunity to explore any inequitable conduct issues in fact discovery, Watson failed to ask either Dr. Zhang or Mr. Maland any questions regarding the allegedly material reference during their respective depositions, and developed no other evidence of inequitable conduct. Watson subsequently moved to amend its complaint on no new information, over a month after fact discovery had closed and almost three months after the pleading amendment deadline, to allege inequitable conduct "upon information and belief." Such behavior is the antithesis of diligence, and is insufficient to demonstrate good cause to modify the Court's Scheduling Order.

3. Watson's motion should also be denied under Fed. R. Civ. P. 15(a) as futile because Watson's proposed pleading fails to state a claim upon which relief could be granted. Watson's proposed amendment fails to plead any facts that could allow the Court to reasonably infer that either Dr. Zhang or Mr. Maland had actual knowledge of the allegedly material

Fed. R. Civ. P. 11(b)(3). In this instance, Watson had already completed fact discovery, and

information, or withheld this information from the Patent Office with the intent to deceive. As such, Watson's proposed inequitable conduct claim fails to state a claim upon which relief could be granted, and the proposed amendment is futile.

V. ARGUMENT

A. Watson's Motion to File an Amended Answer Should be Denied

1. Legal Standards for Inequitable Conduct

Applicants for patents and their legal representatives have a duty of candor, good faith, and honesty in their dealings with the Patent Office. *Cancer Research Tech. v. Barr Labs., Inc.*, C.A. No. 07-457-SLR, 2010 WL 286639 at *13 (D. Del. Jan. 26, 2010) (*citing Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995); 37 C.F.R. § 1.56(a)). The duty of candor, good faith, and honesty includes the duty to submit truthful information and the duty to disclose to the Patent Office information known to patent applicants or their attorneys which is material to the examination of a patent application. *Id.* at *13 (*citing Elk Corp. of Dallas v. GAF Bldg. Materials Corp.*, 168 F.3d 28, 30 (Fed. Cir. 1999)). A breach of this duty constitutes inequitable conduct. *Id.* at *13. In order to establish unenforceability based on inequitable conduct, a defendant must establish by clear and convincing evidence that: (1) the omitted or false information was material to patentability of the invention; (2) the applicant had knowledge of the existence and materiality of the information; and (3) the applicant intended to deceive the Patent Office. *Id.* at *13 (*citing Molins*, 48 F.3d at 1178).

Information is considered material to patentability when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent, or if the information: (1) establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim;

there will be no other opportunity for further investigation or discovery.

or (2) refutes, or is inconsistent with, a position the applicant takes in asserting an argument of patentability or opposing an argument of unpatentability relied on by the Patent Office. *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1314-116 (Fed. Cir. 2006); 37 C.F.R. § 1.56(b). Prior art references that are cumulative to art that was before the examiner during prosecution do not meet the materiality requirement. 37 C.F.R. § 1.56(b).

Inequitable conduct based on an alleged failure to disclose material information to the Patent Office requires a showing that the patent applicant had *actual knowledge* of the undisclosed material information. *Digital Control*, 437 F.3d at 1318. (emphasis added.) It is not sufficient to show that the applicant was generally aware of the allegedly material references – a defendant must show that the individual accused of inequitable conduct knew of the specific information in the references alleged to be material to the claims of the patent at issue. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1330 (Fed. Cir. 2009). “A reference may be many pages long, and its various teachings may be relevant to different applications for different reasons. Thus, one cannot assume that an individual, who generally knew that a reference existed, also knew of the specific material *information* contained in that reference.” *Exergen*, 575 F.3d at 1330. (emphasis original.)

“Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for finding a deceptive intent.” *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996). That is, “the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.” *Kingsdown Med. Consultants v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988).

2. Leave to Amend Should be Denied Because Watson’s Proposed Amendment Fails to Meet the Pleading Requirements of Rule 9(b)

a. Pleading requirements for inequitable conduct under Rule 9(b)

Federal Rule of Civil Procedure 9(b) requires that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). It is appropriate to deny a motion for leave to amend for failing to comply with the pleading requirements of Rule 9(b). *See Exergen*, 575 F.3d at 1331 (affirming the district court’s denial of a motion for leave to amend to allege inequitable conduct for failing to comply with the pleading requirements of Rule 9(b); *Robert Bosch LLC v. Pylon Manufacturing Corp.*, C.A. No. 08-542-SLR, 2009 WL 3366967 at *2 (D. Del. Oct. 19, 2009) (denying a motion for leave to amend for failing to satisfy the pleading requirements for inequitable conduct set forth in *Exergen*).

Inequitable conduct, while a broader concept than fraud, must be pled with particularity under Rule 9(b). *Exergen*, 575 F.3d at 1326 (citing *Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003)).⁴ In pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the Patent Office. *Exergen*, 575 F.3d at 1327. Moreover, although “knowledge” and “intent” may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or the

⁴ Whether inequitable conduct has been adequately pled is a question of Federal Circuit law because it pertains to or is unique to patent law. *Exergen*, 575 F.3d at 1326 (citing *Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356 (Fed. Cir. 2007)).

falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the Patent Office. *Id.* at 1328-29. A “reasonable inference” is one that is plausible and that flows logically from the facts alleged, including any objective indications of candor and good faith. *Id.* at 1329.

Pleading on “information and belief” is permitted under Rule 9(b) only if the pleading sets forth the specific facts upon which the belief is reasonably based. *Exergen*, 575 F.3d at 1330. This Court has permitted allegations of fraud upon information and belief under Rule 9(b), but in instances where fact discovery had not been completed and where the counter-claimant pled additional facts, not upon information and belief, that supported its allegations regarding the counter-defendant’s intent and knowledge. *Sun Microsystems, Inc. v. Versata Enterprises, Inc.*, 630 F. Supp. 2d. 395, 406-407 (D. Del. 2009).

b. Watson’s proposed amendment fails to meet the pleading requirements of Rule 9(b)

Watson’s proposed amendment fails to meet the pleading standards for inequitable conduct set forth in *Exergen*. While Cephalon disputes Watson’s allegation that the ’497 patent was material to the patentability of the ’981 patent, this alleged materiality is irrelevant because, over one month after the close of fact discovery, Watson has *failed to plead any facts* that Dr. Zhang or Mr. Maland: (1) had actual knowledge of the information disclosed in the ’497 patent; or (2) withheld this information with the intent to deceive the Patent Office. Instead, Watson alleges knowledge and intent to deceive only “upon information and belief,” and further fails to set forth any specific facts upon which this belief could be reasonably based. Thus, Watson’s proposed amendment fails to satisfy the pleading standards for inequitable conduct set forth in *Exergen*, and Watson’s motion should be denied. *See Robert Bosch LLC v. Pylon Manufacturing Corp.*, C.A. No. 08-542-SLR, 2009 WL 3366967 at *2 (D. Del. Oct. 19,

2009) (“I decline to allow an inequitable conduct claim to be pursued after the close of discovery when there are insufficient allegations of underlying facts from which I may reasonably infer that the material misrepresentation was made with a specific intent to deceive the PTO.”)

i. Watson has pled no facts regarding Dr. Zhang’s or Mr. Maland’s knowledge of the information disclosed in the ’497 patent

The only facts Watson pleads in the section of its proposed amendment entitled “Knowledge of the ’497 Patent” are the following: Dr. Zhang and Mr. Croft were employees of Anesta at the time the ’071 application was filed (D.I. 53, Exh. A at ¶ 75); Dr. Stanley was a Director at Anesta and Mr. Hague was an employee of Anesta at the time the ’071 application was filed (*Id.* at ¶ 75); Anesta was named as the assignee of the ’981 patent (*Id.* at ¶ 75); the Information Disclosure Statement the applicants submitted to the Patent Office disclosed the ’114 patent, a continuation of the ’737 patent, and the ’497 patent is a continuation-in-part of the ’737 patent (*Id.* at ¶ 76); **[REDACTED]**; and, Dr. Zhang and Mr. Maland had a duty of candor to the Patent Office to disclose all information known to be material to patentability (*Id.* at ¶ 79).

These facts stand for little more than that Dr. Zhang and Mr. Maland worked at the same company as Dr. Stanley and Mr. Hague, the inventors of the ’497 reference. None of these facts, taken separately or in their entirety, provide a reasonable basis for believing that Dr. Zhang or Mr. Maland had actual knowledge of the allegedly material information disclosed in the ’497 patent. Watson’s proposed amendment thus fails to meet the pleading standards for inequitable conduct set forth in *Exergen*, and its motion for leave to amend should be denied. *See Exergen*, 575 F.3d at 1330; *Power Integrations, Inc. v. Fairchild Semiconductor, Int’l, Inc.*, C.A. No. 08-309-JJF, 2009 WL 4928024 at *10 (D. Del. Dec. 18, 2009) (dismissing

inequitable conduct counterclaims when the claimant did not allege facts showing knowledge of the specific material information allegedly withheld from the Patent Office.)

ii. Watson has pled no facts regarding Dr. Zhang's or Mr. Maland's alleged intent to deceive the Patent Office

Watson's allegations regarding Dr. Zhang's and Mr. Maland's purported intent to deceive the Patent Office are even more sparse than its allegations regarding these individuals' knowledge of the allegedly material information. Again, Watson alleges "upon information and belief" that Dr. Zhang and Mr. Maland intentionally withheld the '497 patent from the Patent Office with the intent to deceive. (D.I. 53, Exh. A at ¶ 82.) Again, the supporting facts alleged by Watson do not establish a reasonable basis for believing that Dr. Zhang or Mr. Maland intentionally withheld material prior art from the Patent Office with the intent to deceive. *Exergen*, 575 F.3d at 1330.

The only facts pled by Watson in the section of its proposed amendment entitled "Intent to Deceive the Patent Office" are the following: the '114 patent and the '497 patent have the same named inventors (*Id.* at ¶ 83); the '114 patent was included on the Information Disclosure Statement the applicants submitted to the Patent Office (*Id.* at ¶ 84); a description of what Watson alleges is disclosed in the '114 patent (*Id.* at ¶ 85); a recital of claim 1 of the '114 patent (*Id.* at ¶ 86); the '114 patent is a continuation-in-part of an application that is related to the '497 patent (*Id.* at ¶ 87); the '114 patent, unlike the '497 patent, does not disclose freeze-drying liquid mixtures or wet granulation (*Id.* at ¶ 87); and, Watson's characterization of why the '497 patent was material to the patentability of the '981 patent (*Id.* at ¶ 88).

None of these facts, taken separately or in their entirety, provide a reasonable basis for believing that Dr. Zhang or Mr. Maland knew of the '497 patent, let alone withheld this reference from the Patent Office with the intent to deceive. Intent to deceive can not be

inferred solely from the fact that information was not disclosed to the Patent Office – there must be a factual basis for finding a deceptive intent. *Hebert*, 99 F.3d at 1116. Here, none of the facts alleged by Watson are even remotely related to the scienter of either Dr. Zhang or Mr. Maland. Watson’s proposed amendment fails to meet the pleading standards for inequitable conduct set forth in *Exergen* for this reason as well, and its motion for leave to amend should be denied.

iii. Watson cannot cure the pleading, because the record indicates that Dr. Zhang and Mr. Maland had no knowledge of the ’497 patent

Watson’s decision to allege knowledge and intent on information and belief after a full opportunity to take discovery is more troublesome in light of the evidence in the record that contradicts their allegations. [REDACTED.] Watson did not ask either Dr. Zhang or Mr. Maland a single question about the ’497 patent during their respective depositions, and there is no other evidence upon which Watson could have reasonably formed a belief that either Dr. Zhang or Mr. Maland had actual knowledge of the information disclosed in the ’497 patent. There is also no information in the record to suggest that Dr. Zhang or Mr. Maland knew that the ’497 patent was material to the patentability of the ’981 patent but withheld it from the Patent Office with the intent to deceive, as Watson tacitly admits by the paucity of relevant information in its proposed pleading.

In sum, because Watson’s proposed pleading does not satisfy the requirements of Rule 9(b), the Court should not allow the amendment.

3. Leave to Amend Under Rule 16(b) Should Be Denied Because Watson Has Not Shown Good Cause For Its Proposed Amendment

a. Legal standards for moving to amend the scheduling order under Rule 16(b)

Motions to amend which, in effect, operate to modify the scheduling order are controlled by Fed. R. Civ. P. 16(b). *E. Minerals & Chem. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000). After a pleading deadline has passed, a scheduling order may be modified only for good cause and with the judge's consent. Fed. R. Civ. P. 16(b)(4). "Good cause" exists when the schedule cannot reasonably be met despite the diligence of the party seeking the extension. Fed. R. Civ. P. 16(b)(4) Advisory Committee's Notes (1983 amendments). "In contrast to Rule 15(a), the good cause standard under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party." *Roquette Freres v. SPI Pharma, Inc.*, C.A. No. 06-540-GMS, 2009 WL 1444835 at *4 (D. Del. May 21, 2009).

b. Watson has not established good cause for modifying the Court's Scheduling Order

Watson's claims of diligence are nothing more than conclusory allegations that parrot the elements of an inequitable conduct claim. (*See, e.g.*, D.I. 53 at 4: "On January 19, 2010, Watson took the deposition of Mr. Lynn Maland and learned that...Mr. Maland failed to disclose material information to the PTO with the intent to deceive.") What exactly Watson learned to suddenly justify the late amendment, Watson does not say. In reality, Watson did not ask Mr. Maland a single question regarding the '497 patent, the subject of the alleged inequitable conduct, during Mr. Maland's deposition. Watson also did not ask Dr. Zhang any questions regarding the '497 patent at his deposition on January 14, 2010, or at his deposition on December 10 and 11, 2009. The only evidence Watson obtained from the depositions of these individuals relevant to its proposed inequitable conduct claim was **[REDACTED.]**

Tellingly, neither Watson's motion nor its proposed pleading identifies the information "discovered" in the depositions of these individuals, because none of the testimony obtained supports Watson's proposed inequitable conduct claim.

Watson had an opportunity to fully explore any inequitable conduct issues in fact discovery, including through the depositions of the '981 patent inventors, Mr. Maland, and Mr. Krieger, the attorney who prosecuted the '071 application. Instead, Watson did not elicit testimony from any of these individuals regarding the '497 patent, developed no other evidence of inequitable conduct in the fact discovery period, and moved to amend its complaint over a month after fact discovery closed to allege inequitable conduct "upon information and belief." Such behavior is the antithesis of diligence.

Watson's reliance on *Enzo Life Sciences* and *Roquette Freres* is misplaced. This Court has permitted amendment after the deadline for amending pleadings when a party has pled inequitable conduct ***based on new facts*** which were recently confirmed by depositions of the inventors. *Roquette Freres*, 2009 WL 1444835 at *5; *Enzo Life Sciences, Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 489 (D. Del. 2003); *see also Cordance Corp. v. Amazon.com, Inc.*, 255 F.R.D. 366, 372 (D. Del. 2009). As explained above, and as is evident from Watson's motion and proposed pleading, there were no facts obtained from the depositions of Dr. Zhang or Mr. Maland that support Watson's proposed inequitable conduct claim.

In sum, Watson has not established that it was diligent in seeking amendment, and therefore has not established good cause to modify the Court's Scheduling Order. Watson's motion for leave to amend should also be denied under Rule 16(b).

4. Watson's Motion Should Be Denied Under Rule 15(a)

a. Legal standards for moving to amend under Rule 15(a)

Leave to amend under Fed. R. Civ. P. 15(a) "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). Among the grounds that could justify a denial of leave to amend are undue delay, bad faith, dilatory motive, prejudice, and futility. *Id.* at 1434; *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir. 1993).

"Futility" means that the complaint, as amended, would fail to state a claim upon which relief could be granted. *In re Burlington Coat Factory*, 114 F.3d at 1434. In determining whether a claim would be futile, "the district court applies the same standard of legal sufficiency as applies under [Federal] Rule [of Civil Procedure] 12(b)(6)." *Id.* at 1434. Under the Rule 12(b)(6) standard, a court should "accept as true all of the allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the plaintiff." *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997). However, "a court need not credit a complaint's 'bald assertions' or 'legal conclusions.'" *Id.* at 906. The factual allegations in the complaint "must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). To survive a motion to dismiss, a complaint must allege sufficient facts, accepted as true, to "state a claim to relief that is plausible on its face." *Id.* at 547. A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1940 (2009).

b. Watson's proposed amendment is futile

Watson's proposed amendment is futile because it fails to state a claim upon which relief could be granted. As indicated above, one month after the close of fact discovery, Watson has failed to plead any facts that could allow the Court to reasonably infer that Dr. Zhang or Mr. Maland: (1) had actual knowledge of the information disclosed in the '497 patent; or (2) withheld this information with the intent to deceive the Patent Office.

i. Watson has pled no facts that permit a reasonable inference that Dr. Zhang or Mr. Maland had knowledge of the information disclosed in the '497 patent

The same shortcomings that doom Watson's pleading under Rule 9(b) also demonstrate futility. Even accepting all of the facts pled by Watson as true, Watson has at best alleged: (1) Dr. Zhang, Mr. Croft, Dr. Stanley, and Mr. Hague were all Anesta employees, and the '981 patent was assigned to Anesta; (2) the applicants disclosed a patent that is in the same family as the '497 patent to the Patent Office; (3) [REDACTED]; (4) [REDACTED] and (5) Dr. Zhang and Mr. Maland has a duty of candor to the Patent Office. (D.I. 53, Exh. A at ¶¶ 75-79.) None of these facts permit a reasonable inference that Dr. Zhang or Mr. Maland had knowledge of the allegedly material information disclosed in the '497 patent. Because Watson fails to adequately plead knowledge of the allegedly material reference, it cannot state a claim upon which relief could be granted, and the proposed amendment is futile.

ii. Watson has pled no facts that permit a reasonable inference that Dr. Zhang or Mr. Maland withheld material information from the Patent Office with the intent to deceive

Watson's proposed pleading is also futile because it pleads no facts that permit a reasonable inference that Dr. Zhang or Mr. Maland withheld the '497 patent from the Patent Office with the intent to deceive. For the same reasons as stated in Section V(A)(2)(b)(ii)

above, even accepting all of the facts pled by Watson as true, none of the facts pled are related to the scienter of either Dr. Zhang or Mr. Maland, and none of facts pled can support a reasonable inference that Dr. Zhang or Mr. Maland acted with an intent to deceive the Patent Office. Thus, Watson's proposed inequitable conduct claim fails to state a claim upon which relief could be granted, and Watson's motion should be denied as futile.

c. Cephalon would be prejudiced by Watson's proposed amendment

Cephalon would be unfairly prejudiced if the Court were to grant Watson leave to amend to assert its proposed inequitable conduct claim. Watson sought this amendment after the close of discovery, after opening expert reports were served, and with trial less than two months away. As Cephalon showed above, Watson's pleading at bottom only alleges that Dr. Zhang and Mr. Maland should have known of what was supposedly material in the '497 patent because Dr. Stanley, Mr. Hague, Dr. Zhang, and Mr. Maland all worked for the same company. That pleading could have been filed at the beginning of this case, not the end (although it would have been inadequate then too). The trial is set for only a week, and with three patents-in-suit there are already a large number of issues for Cephalon to present to the Court to support its case and to rebut Watson's case. Cephalon is working diligently to streamline that case so only key issues are presented to the Court for decision. Watson's untimely effort to plead this unsupported defense has and will prejudice trial preparation, and will prejudice Cephalon's ability to effectively try the issues that were timely joined. Watson's motion to amend should also be denied on grounds of unfair prejudice to Cephalon.

VI. CONCLUSION

Fact discovery in this action is closed, and Watson has already obtained all of the discovery regarding any alleged inequitable conduct that it has sought, including almost three

days of deposing Dr. Zhang, one day of deposing Mr. Maland, and the production of more than 150,000 pages of documents. That Watson seeks to plead inequitable conduct now almost entirely upon information and belief, unsupported by facts, after the close of fact discovery demonstrates that there is no evidence that either Dr. Zhang or Mr. Maland committed fraud upon the Patent Office. The Court should deny Watson's motion to amend and its deficient proposed pleading now for failing to satisfy Rule 9(b), Rule 16(b), and Rule 15(a) for the reasons stated above, rather than waste trial resources hearing a claim that can not even be adequately pled. For the reasons set forth above, Cephalon respectfully requests that the Court deny Watson's motion for leave to file an amended answer and counterclaims.

Respectfully submitted,

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